

REMARKS

The high osmolyte no-rub cleaning and disinfecting solution disclosed and claimed in the present application has an effective amount of an osmolyte adjusting agent to increase the osmolality of the total solution for cleaning enhancement without adversely affecting the antimicrobial efficacy of the cleaning and disinfection solution. Demonstrating the effect of increasing osmolality on the cleaning and disinfecting efficacy of the solution, applicants conducted a number of experiments, which are disclosed in the subject specification. The results of the experiments clearly show that cleaning is enhanced with increased osmolality.

Claims 1, 9, 17 and 19 have been amended to include the limitation of an osmolyte adjusting agent in a concentration sufficient to increase osmolality of the total solution to a level higher than that of an eye's lacrimal fluids or an osmotic value greater than 300 mOsm/kg, to enhance the cleaning efficacy of the solution without inhibiting the antimicrobial efficacy of the solution. Support for the current amendments may be found on page 6, lines 27 and 28, in addition to other locations throughout the specification. Claims 7, 10 and 13-16 have been amended to correct informalities of improper antecedent basis. Claim 6 has been cancelled.

Claims 1-19 stand rejected under 35 U.S. C. 103(a) as being unpatentable over Riedhammer et al., U.S. Patent Number 4,820,352 (Riedhammer). Applicants respectfully traverse the subject rejection of claims 1-19 under 35 U.S.C. 103(a).

Riedhammer teaches an aqueous cleaning dispersion with a **tonicity that may be modified with 0.9 percent saline to that of lacrimal fluids** to avoid lens discomfort if not thoroughly washed from the lens (Col 5, lines 13-18). Human lacrimal fluid has an osmolality of 300 mOsm/kg. Riedhammer teaches osmolyte agents such as sodium chloride in the amount of 6.75 g per one liter of water to adjust the osmolality of the solution to that of lacrimal fluids, i.e., 300 mOsm/kg. Riedhammer does not teach the high osmolyte improved cleaning solutions of the present invention.

Riedhammer also teaches that aqueous cleaning and conditioning solutions may be effectively used in removing and dispersing protein and lipid tear film deposits on both hard and soft type contact lenses **by any of the well-recognized methods** (Col. 5, lines 37-40). The well-recognized methods are the methods approved by the U.S. Food and Drug Administration (FDA) for cleaning contact lenses. Such approved or well-recognized methods include rubbing. Specifically, Riedhammer teaches rubbing a lens with cleaning solution followed by soaking at room temperature for a period of four to twelve hours (Col. 5, lines 42-45). Riedhammer does not teach the high osmolyte improved cleaning solutions of the present invention that allow for **unconventional “no-rub” cleaning**. The claimed no-rub solutions of the present invention thereby differ significantly from the teachings of Riedhammer for solutions having an osmotic value or tonicity **like that of lacrimal fluids** requiring rubbing for effective contact lens cleaning. Accordingly, the unique no-rub solutions of the present invention with osmolyte adjusting agents in concentrations sufficient to enhance the cleaning properties of the solutions without adversely affecting antimicrobial efficacy as disclosed and claimed in the subject application differs significantly from the teachings of Riedhammer. For these reasons in addition to others not set forth herein, the rejection of claims 1-19 under 35 U.S.C. 103(a) is thereby inappropriate. Withdrawal of the rejection claims 1-19 under 35 U.S.C. 103(a) is respectfully requested.

Pending claims 1-5 and 7-19 as now written are believed to be patentable.
Allowance of pending claims 1-5 and 7-19 is thereby respectfully requested.

Should there be any questions regarding this correspondence, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rita D. Vacca". The signature is fluid and cursive, with the first name "Rita" and last name "Vacca" clearly distinguishable.

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